

110TH CONGRESS
2D SESSION

S. 2990

To amend title XVIII of the Social Security Act to improve access of Medicare beneficiaries to intravenous immune globulins.

IN THE SENATE OF THE UNITED STATES

MAY 7, 2008

Mr. KERRY (for himself, Mr. ALEXANDER, and Ms. STABENOW) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to improve access of Medicare beneficiaries to intravenous immune globulins.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medicare IVIG Access Act of 2008”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Medicare payment for intravenous immune globulins.

Sec. 4. Coverage and payment of intravenous immune globulin in the home.

Sec. 5. Reports.

Sec. 6. Offset.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Intravenous immune globulin (IVIG) is a
4 human blood plasma derived product, which over the
5 past 25 years has become an invaluable therapy for
6 many primary immunodeficiency diseases, as well as
7 a number of neurological, autoimmune, and other
8 chronic conditions and illnesses. For many of these
9 disorders, IVIG is the most effective and viable
10 treatment available, and has dramatically improved
11 the quality of life for persons with these conditions
12 and has become a life-saving therapy for many.

13 (2) The Food and Drug Administration recog-
14 nizes each IVIG brand as a unique biologic. The dif-
15 ferences in basic fractionation and the addition of
16 various modifications for further purification, sta-
17 bilization, and virus inactivation/removal yield clear-
18 ly different biological products. As a result, IVIG
19 therapies are not interchangeable, with patient toler-
20 ance differing from one IVIG brand to another.

21 (3) The report of the Office of the Assistant
22 Secretary for Planning and Evaluation of the De-
23 partment of Health and Human Services, “Analysis
24 of Supply, Distribution, Demand, and Access Issues

1 Associated with Immune Globulin Intravenous
2 (IGIV)”, that was issued in May 2007, found that
3 IVIG manufacturing is complex and requires sub-
4 stantial up-front cash outlay and planning and takes
5 between 7 and 12 months from plasma collection at
6 donor centers to lot release by the Food and Drug
7 Administration.

8 (4) The Medicare Prescription Drug, Improve-
9 ment, and Modernization Act of 2003 (Public Law
10 108–173; 117 Stat. 2066) changed Medicare’s reim-
11 bursement methodology for IVIG from average
12 wholesale price (AWP) to average sales price plus 6
13 percent (ASP+6 percent), effective January 1,
14 2005, for physicians, and January 1, 2006, for hos-
15 pital outpatient departments, thereby reducing reim-
16 bursement rates paid to those providers of IVIG on
17 behalf of Medicare beneficiaries.

18 (5) An April 2007 report of the Office of In-
19 spector General of the Department of Health and
20 Human Services, “Intravenous Immune Globulin:
21 Medicare Payment and Availability”, found that
22 Medicare reimbursement for IVIG was inadequate to
23 cover the cost many providers must pay for the
24 product. During the third quarter of 2006, 44 per-
25 cent of IVIG sales to hospitals and 41 percent of

1 sales to physicians by the 3 largest distributors oc-
2 curred at prices above Medicare payment amounts.

3 (6) The report of the Office of the Assistant
4 Secretary for Planning and Evaluation of the De-
5 partment of Health and Human Services, “Analysis
6 of Supply, Distribution, Demand, and Access Issues
7 Associated with Immune Globulin Intravenous
8 (IGIV)” notes that, after the new reimbursement
9 rules for physicians were instituted in 2005, 42 per-
10 cent of Medicare beneficiaries who had received their
11 IVIG treatment in their physician’s office at the end
12 of 2004 were shifted to the hospital outpatient set-
13 ting by the beginning of 2006. This shift in site of
14 care has resulted in a lack of continuity of care and
15 has had an adverse impact on health outcomes and
16 quality of life.

17 (7) The Office of Inspector General of the De-
18 partment of Health and Human Services also re-
19 ported that 61 percent of responding physicians in-
20 dicated that they had sent patients to hospitals for
21 IVIG treatment, largely because of their inability to
22 purchase IVIG at prices below the Medicare pay-
23 ment amounts. In addition, the Office of Inspector
24 General found that some physicians had stopped
25 providing IVIG to Medicare beneficiaries altogether.

1 (8) The Office of Inspector General’s 2007 re-
2 report concluded that whatever improvement some
3 providers saw in the relationship of Medicare reim-
4 bursement for IVIG to prices paid during the first
5 3 quarters of 2006 would be eroded if manufactur-
6 ers were to increase prices for IVIG in the future.

7 (9) The Centers for Medicare & Medicaid Serv-
8 ices, in recognition of dislocations experienced by pa-
9 tients and providers in obtaining IVIG since the
10 change to the ASP+6 reimbursement methodology,
11 has provided a temporary additional payment during
12 2006 and 2007 for IVIG preadministration-related
13 services to compensate physicians and hospital out-
14 patient departments for the extra resources they
15 have had to expend in locating and obtaining appro-
16 priate IVIG products and in scheduling patient infu-
17 sions.

18 (10) Approximately 10,000 Medicare bene-
19 ficiaries receive IVIG treatment for their primary
20 immunodeficiency disease in a variety of different
21 settings. Those beneficiaries have no other effective
22 treatment for their condition.

23 (11) The Medicare Prescription Drug, Improve-
24 ment, and Modernization Act of 2003 established an
25 IVIG home infusion benefit for persons with primary

1 immune deficiency disease, paying only for IVIG and
2 specifically excluding coverage of items and services
3 related to administration of the product.

4 (12) The report of the Office of the Assistant
5 Secretary for Planning and Evaluation of the De-
6 partment of Health and Human Services, “Analysis
7 of Supply, Distribution, Demand, and Access Issues
8 Associated with Immune Globulin Intravenous
9 (IGIV)”, noted that, because of limitations in the
10 Medicare Prescription Drug, Improvement, and
11 Modernization Act of 2003 provision, Medicare’s
12 IVIG home infusion benefit is not designed to pro-
13 vide reimbursement for more than the cost of IVIG
14 and does not cover the cost of infusion services (such
15 as nursing and clinical services and supplies) in the
16 home. As a consequence, the report found that home
17 infusion providers generally do not accept new pa-
18 tients who have primary immune deficiency disease
19 and only have Medicare coverage. These limitations
20 in service are caused by health care providers—

21 (A) not being able to acquire IVIG at
22 prices at or below the Medicare part B reim-
23 bursement level; and

24 (B) not being reimbursed for the infusion
25 services provided by a nurse.

1 (13) Access to home infusion of IVIG for pa-
2 tients with primary immune deficiency disease, who
3 have a genetic or intrinsic defect in their human im-
4 mune system, will reduce their exposure to infections
5 at a time when their antibodies are compromised
6 and will improve the quality of care and health of
7 the patient.

8 **SEC. 3. MEDICARE PAYMENT FOR INTRAVENOUS IMMUNE**
9 **GLOBULINS.**

10 (a) IN GENERAL.—Section 1842(o) of the Social Se-
11 curity Act (42 U.S.C. 1395u(o)) is amended—

12 (1) in paragraph (1)(E)(ii), by inserting “, plus
13 an additional amount (if applicable) under para-
14 graph (7)” before the period at the end;

15 (2) by redesignating paragraph (7) as para-
16 graph (8); and

17 (3) by inserting after paragraph (6) the fol-
18 lowing new paragraph:

19 “(7)(A) Not later than 6 months after the date
20 of enactment of the Medicare IVIG Access Act of
21 2008, the Secretary shall—

22 “(i) collect data on the differences, if any,
23 between payments to physicians for intravenous
24 immune globulin under paragraph (1)(E)(ii)

1 and costs incurred by physicians for furnishing
2 such products; and

3 “(ii) review available data, including survey
4 and pricing data collected by the Federal Gov-
5 ernment and data presented by members of the
6 intravenous immune globulin community on the
7 access of individuals eligible for services under
8 this part to intravenous immune globulin and
9 the differences described in clause (i).

10 “(B) Subject to subparagraph (C), in the case
11 of intravenous immune globulin furnished on or
12 after the date of enactment of this paragraph, the
13 Secretary shall continue the IVIG preadministration-
14 related services payment established under the final
15 rule promulgated by the Secretary in the Federal
16 Register on November 27, 2007 (72 Fed. Reg.
17 66254), until such time as the Secretary determines
18 that payment for intravenous immune globulin is
19 adequate.

20 “(C) Upon collection of data and completion of
21 the review under subparagraph (A), the Secretary
22 shall, during a 2-year period beginning not later
23 than 7 months after such date of enactment, pro-
24 vide, if appropriate, to physicians furnishing intra-
25 venous immune globulins, a payment, in addition to

1 the payment under paragraph (1)(E)(ii) and instead
 2 of the IVIG preadministration-related services pay-
 3 ment under subparagraph (B), for all items related
 4 to the furnishing of intravenous immune globulin, in
 5 an amount the Secretary determines to be appro-
 6 priate.”.

7 (b) AS PART OF HOSPITAL OUTPATIENT SERV-
 8 ICES.—Section 1833(t)(14) of such Act (42 U.S.C.
 9 1395l(t)(14)) is amended—

10 (1) in subparagraph (A)(iii), by striking “sub-
 11 paragraph (E)” and inserting “subparagraphs (E)
 12 and (I)”;

13 (2) by adding at the end the following new sub-
 14 paragraph:

15 “(I) ADDITIONAL PAYMENT FOR INTRA-
 16 VENOUS IMMUNE GLOBULIN.—

17 “(i) DATA COLLECTION AND RE-
 18 VIEW.—Not later than 6 months after the
 19 date of enactment of the Medicare IVIG
 20 Access Act of 2008, the Secretary shall—

21 “(I) collect data on the dif-
 22 ferences, if any, between payments of
 23 intravenous immune globulin under
 24 subparagraph (A)(iii) and costs in-

1 curred by a hospital for furnishing
2 such products; and

3 “(II) review available data, in-
4 cluding survey and pricing data col-
5 lected by the Federal Government and
6 data presented by members of the in-
7 travenous immune globulin commu-
8 nity on the access of individuals eligi-
9 ble for services under this part to in-
10 travenous immune globulin and the
11 differences described in subclause (I).

12 “(ii) CONTINUATION OF SPECIAL PAY-
13 MENT RULE.—Subject to clause (iii), in the
14 case of intravenous immune globulin fur-
15 nished on or after the date of enactment of
16 this subparagraph, the Secretary shall con-
17 tinue the IVIG preadministration-related
18 services payment established under the
19 final rule promulgated by the Secretary in
20 the Federal Register on November 27,
21 2007 (72 Fed. Reg. 66697), until such
22 time as the Secretary determines that pay-
23 ment for intravenous immune globulin is
24 adequate.

1 “(iii) ADDITIONAL PAYMENT AUTHOR-
 2 ITY.—Upon collection of data and comple-
 3 tion of the review under clause (i), the Sec-
 4 retary shall, during a 2-year period begin-
 5 ning not later than 7 months after such
 6 date of enactment, provide, if appropriate,
 7 to hospitals furnishing intravenous immune
 8 globulin as part of a covered OPD service,
 9 in addition to the payment under subpara-
 10 graph (A)(iii) and instead of the IVIG
 11 preadministration-related services payment
 12 under clause (ii), for all items related to
 13 the furnishing of intravenous immune glob-
 14 ulin, in an amount the Secretary deter-
 15 mines to be appropriate.”.

16 **SEC. 4. COVERAGE AND PAYMENT OF INTRAVENOUS IM-**
 17 **MUNE GLOBULIN IN THE HOME.**

18 (a) IN GENERAL.—Section 1861 of the Social Secu-
 19 rity Act (42 U.S.C. 1395x) is amended—

- 20 (1) in subsection (s)(2)(Z), by inserting “and
 21 items and services related to the administration of
 22 intravenous immune globulin” after “globulin”; and
 23 (2) in subsection (zz), by striking “but not in-
 24 cluding items or services related to the administra-
 25 tion of the derivative,”.

1 (b) PAYMENT FOR INTRAVENOUS IMMUNE GLOBULIN
2 ADMINISTRATION IN THE HOME.—Section 1842(o) of the
3 Social Security Act (42 U.S.C. 1395u(o), as amended by
4 section 3), is amended—

5 (1) in paragraph (1)(E)(ii), by striking “para-
6 graph (7)” and inserting “paragraph (7) or (8)”;

7 (2) by redesignating paragraph “(8)” as para-
8 graph “(9)”; and

9 (3) by inserting after paragraph (7) the fol-
10 lowing new paragraph:

11 “(8)(A) Subject to subparagraph (B), in the
12 case of intravenous immune globulins described in
13 section 1861(s)(2)(Z) that are furnished on or after
14 January 1, 2008, the Secretary shall provide for a
15 separate payment for items and services related to
16 the administration of such intravenous immune
17 globulins in an amount that the Secretary deter-
18 mines to be appropriate based on a review of avail-
19 able published and unpublished data and informa-
20 tion, including the Study of Intravenous Immune
21 Globulin Administration Options: Safety, Access,
22 and Cost Issues conducted by the Secretary (CMS
23 Contract #500–95–0059). Such payment amount
24 may take into account the following:

1 “(i) Pharmacy overhead and related ex-
2 penses.

3 “(ii) Patient service costs.

4 “(iii) Supply costs.

5 “(B) The separate payment amount provided
6 under this paragraph for intravenous immune
7 globulins furnished in 2009 or a subsequent year
8 shall be equal to the separate payment amount de-
9 termined under this paragraph for the previous year
10 increased by the percentage increase in the medical
11 care component of the consumer price index for all
12 urban consumers (United States city average) for
13 the 12-month period ending with June of the pre-
14 vious year.”.

15 **SEC. 5. REPORTS.**

16 (a) **REPORT BY THE SECRETARY.**—Not later than 7
17 months after the date of enactment of this Act, the Sec-
18 retary of Health and Human Services (in this section re-
19 ferred to as the “Secretary”) shall submit a report to Con-
20 gress on the following:

21 (1) The results of the data collection and review
22 conducted by the Secretary under subparagraph (A)
23 of section 1842(o)(7) of the Social Security Act, as
24 added by section 3(a), and clause (i) of section
25 1833(t)(14)(I) of such Act, as added by section 3(b).

1 (2) Whether the Secretary plans to use the au-
2 thority under subparagraph (C) of such section
3 1842(o)(7) and clause (iii) of such section
4 1833(t)(14)(I) to provide an additional payment to
5 physicians furnishing intravenous immune globulins.

6 (b) MEDPAC REPORT.—Not later than 2 years after
7 the date of enactment of this Act, the Medicare Payment
8 Advisory Commission shall submit a report to the Sec-
9 retary and to Congress that contains the following:

10 (1) In the case where the Secretary has used
11 the authority under sections 1842(o)(7)(C) and
12 1833(t)(14)(I)(iii) of the Social Security Act, as
13 added by subsections (a) and (b), respectively, of
14 section 3 to provide an additional payment to physi-
15 cians furnishing intravenous immune globulins dur-
16 ing the preceding year, an analysis of whether bene-
17 ficiary access to intravenous immune globulins under
18 the Medicare program under title XVIII of the So-
19 cial Security Act has improved as a result of the
20 Secretary's use of such authority.

21 (2) An analysis of the appropriateness of imple-
22 menting a new methodology for payment for intra-
23 venous immune globulins under part B of title
24 XVIII of the Social Security Act (42 U.S.C. 1395k
25 et seq.).

1 (3) An analysis of the feasibility of reducing the
2 lag time with respect to data used to determine aver-
3 age sales price under section 1847A of the Social
4 Security Act (42 U.S.C. 1395w-3a).

5 (4) Recommendations for such legislation and
6 administrative action as the Medicare Payment Ad-
7 visory Commission determines appropriate, including
8 recommendations for such legislation and adminis-
9 trative action as the Commission determines is nec-
10 essary to implement any methodology analyzed
11 under paragraph (2).

12 **SEC. 6. OFFSET.**

13 Section 1861(n) of the Social Security Act (42 U.S.C.
14 1395x(n)) is amended by adding at the end the following:
15 “Such term includes disposable drug delivery systems, in-
16 cluding elastomeric infusion pumps, for the treatment of
17 colorectal cancer.”.

○